# Guidance for Food Processing / Packaging in Michigan Food Service Establishments June, 2005

Michigan Department of Agriculture Food and Dairy Division

# Table of Contents

General considerations	1
Role of the establishment's person-in-charge	2
Local health department role	2
Processing regulations	2
Reviewing a process for food safety	3
Additional sources of information	4
Product specific information sheets	
Jams, jellies and preserves	
Sandwiches	7
Low acid or acidified foods	9
Soups, pizza	11
Dry shelf stable foods (i.e. baked goods, dry snack foods, candy)	13
Appendix	
Processing information sheet	15
Processing related variances	16

Food service operators occasionally wish to prepare, package and label food for later use by the consumer. This is considered to be food processing / packaging. Packaged means bottled, canned, cartoned, securely bagged, or securely wrapped. Packaged does not include a wrapper, carry-out box, or other non-durable container used to containerize food with the purpose of facilitating food protection during service and receipt of the food by the consumer.

The local health department (LHD) will provide assistance in determining the steps necessary to conduct a lawful and safe operation. The establishment owner must comply with various regulations and is advised to consult with their local health department prior to beginning processing / packaging operations. A licensed food service establishment doesn't require additional state licensure to conduct processing / packaging operations. However, there are a number of state and federal laws that need to be met, depending upon the product and process.

Should an existing licensed establishment begin processing / packaging operations that do not comply with the various processing laws, enforcement action may be conducted by the: local health department, Michigan Department of Agriculture (MDA), Food and Drug Administration (FDA) and/or United States Department of Agriculture (USDA).

#### **General considerations:**

The following must be considered before adding a processing / packaging operation to an existing food service establishment:

- The existing establishment must have adequate capacity to add the processing / packaging operation. For example:
  - a. Is there enough room to add any additional equipment needed?
  - b. Is there enough space for storage of raw materials, finished product and packaging materials?
  - c. Does the proposed preparation / processing area allow for adequate separation of raw and ready-to-eat foods?
- 2. All processing / packaging establishments must comply with 21 CFR 110, Current Good Manufacturing Practice in Manufacturing, Packaging, or Holding Human Food. Establishments that comply with the Michigan Food Law (MFL) and 1999 FDA Food Code (FC) will automatically comply with most parts of 21 CFR 110. Establishments that don't comply with the MFL and FC must make improvements before adding additional operations. Review 21 CFR 110 to determine if there are any sections applicable to the proposed processing that are not already covered by the MFL and FC.
- 3. A variance must be applied for and obtained from the local health department if required by FC 3-502.11. Variances are required for: smoking for preservation, curing food, brewing alcoholic beverages, using additives such as vinegar for preservation or to render a food not potentially hazardous, using reduced oxygen packaging if FC 3-502.12 will not be met or custom processing animals for a consumer's personal use. See FC 8-103.10 & .11 for additional variance information.
- 4. Plan approval must be received for any construction or remodeling.
- 5. Standard operating procedures (SOP's) must be established prior to beginning processing operations. Standardized procedures are essential for an establishment to comply with applicable regulations and produce a consistently

safe product. Written SOP's are encouraged for all processing operations. Written SOP's are required for facilities seeking plan approval. See MDA's "Plan Submission Instructions" for SOP guidance at:

http://www.mda.state.mi.us/industry/fooddata/FSSS/0411 SOP Guidance Memo.pdf

## Role of the establishment's person-in-charge (PIC)

- Provide basic information to the LHD, such as: type of food; whether the food is
  potentially hazardous or not; product's characteristics (i.e. fully cooked soup, liquid,
  finished pH of 5.7, water activity of 0.98, etc.); storage temperature during
  warehousing; how product will be sold (refrigerated, frozen or shelf-stable); shelf life
  and how determined; how product will be packaged, coded, labeled; method of sale,
  intended consumer, etc. The information form located in the appendix may be used
  to summarize basic information on a proposed processing operation.
- Identify all the manufacturing steps for each food to be processed, using such tools as: flow diagrams; processing authority (consultant) evaluation; establishment plans; explanations of specialized processing, monitoring or testing equipment; and other supporting documents.
- Be the expert in processing the food.
- Identify potential food safety hazards (microbiological, chemical, physical) and how they will be controlled.
- Assure the food processes used result in a safe product.

#### **Local Health Department Role**

Review a proposed process and establishment for food safety and compliance with applicable regulations and to review variance requests, as needed. Local health department staff will contact their MDA food service consultant for assistance, as needed. Neither the LHD, MDA nor the FDA provide approval of a proposed process.

#### \*Processing Regulations

State regulation 569 applies to processing of smoked fish.

Food service establishments that process food must comply with the Michigan Food Law (MFL) and 1999 FDA Food Code (FC).

- o FC 3-502.11-.12 covers food processing.
- MFL section 1105 contains a definition of adulterated food.

The Michigan Food Law, chapters 7 and 8 state, in part:

## 289.7101 Compliance with federal regulations; exception

Subject to section 1119(2), a food processing plant shall comply with the regulations of the food and drug administration in 21 C.F.R. part 110, except that refrigerated potentially hazardous food shall be stored at 4.4 degrees centigrade (40 degrees Fahrenheit) or below.

#### 289.7103 Processing low-acid foods; requirements.

- (1) All thermally processed, low-acid foods that are packaged in hermetically sealed containers shall be processed in a licensed commercial food establishment.
- (2) All processors of acidified, low-acid foods packaged in hermetically sealed containers shall comply with the regulations of the U.S. food and drug administration in 21 C.F.R. part 114.

- (3) All thermally processed, low-acid foods that are packaged in hermetically sealed containers shall comply with the regulations of the U.S. food and drug administration in 21 C.F.R. part 113.
- (4) Hermetically sealed packages shall be handled to maintain product and container integrity.
- 289.7105 Processor of smoked fish; variance; waiver.

The requirement that a processor of smoked fish obtain a variance under the smoked fish rules is waived if the processor demonstrates compliance with 21 C.F.R. part 123, the "seafood HACCP plan".

289.7111 Packaged food; compliance with federal regulations.

Packaged food shall comply with standard of identity requirements in 21 C.F.R. parts 131 to 169 and the definitions and standards of identity or composition contained in 9 C.F.R. part 319, and the general requirements in 21 C.F.R. part 130 and subpart A of part 319 of title 9 of the Code of Federal Regulations except as modified or rejected by this act or rules promulgated under this act.

289.8101 Packaged food; label requirements.

Packaged food shall be labeled as specified in 21 C.F.R. part 101, 9 C.F.R. part 317, and subpart N of part 381 of title 9 of the Code of Federal Regulations, and as specified under sections 3-202.17 and 3-202.18 of the food code.

Links to regulations:

Most regulations: http://michigan.gov/mda/1,1607,7-125-1568 2387 2435-12817--,00.html#code

FDA food labeling & standard of Identity regulations:

21 cfr parts 100-169 : <a href="http://www.access.gpo.gov/nara/cfr/waisidx">http://www.access.gpo.gov/nara/cfr/waisidx</a> 03/21cfrv2 03.html
9 cfr part 319: <a href="http://www.access.gpo.gov/nara/cfr/waisidx">http://www.access.gpo.gov/nara/cfr/waisidx</a> 04/9cfr319 04.html

MDA Labeling Guide: http://www.michigan.gov/mda/0,1607,7-125-1568 2388-15868--,00.html

#### Reviewing a Food Process for Food Safety

The primary focus is that the proposed processed food will be safe. The primary responsibility for food safety lies with the person-in-charge (PIC). The PIC is responsible for identifying potential food safety hazards and proposing control methods. The PIC is required to work with a process specialist (consultant) when processing low acid or acidified foods under 21 CFR's 113 or 114. The PIC may wish to consult with a process specialist even when not required in order to assure a safe process is being proposed. Methods of locating locate a process specialist include: conducting an internet search, contact the "MSU Cooperative Extension Service".

(<a href="http://www.msue.msu.edu/msue/ctyentpg/ctyunits.html">http://www.msue.msu.edu/msue/ctyentpg/ctyunits.html</a>) or contact a related processor's association. The regulatory agency will review the process to determine that food safety has been assured.

A few examples of how process variations can affect food safety are provided below. These examples illustrate why a carefully designed and closely followed process is critical to food safety.

### Example 1:

A restaurant owner decides to package, label and sell a popular vegetable soup. To get started, the proposal is to put the soup in a glass jar with a metal lid and sell refrigerated. The product will be labeled to keep refrigerated and use within Food Code date marking time limits.

Method 1: Place cooled (i.e. 41° F) soup into cold jars and screw on lid. Label and refrigerate.

Method 2: Place hot soup (i.e. 190° F) into warm jar and screw on lid. Label and refrigerate.

Method 1 <u>does not</u> create a food safety hazard. Method 2 <u>does create</u> a food safety hazard. The hot soup will consume the air and cause the lid to seal onto the container. Lack of air creates an environment where *Clostridium botulinum* organisms are not controlled. Hot packaging results in reduced oxygen packaging which requires a Food Code variance and possible development of a HACCP plan.

### Example 2:

A restaurant owner decides to package, label and sell a popular dressing containing garlic, oil and vinegar.

Method 1: Press fresh garlic. Add vinegar. Stabilize pH to <4.6. Monitor pH. Add oil. Method 2: Press fresh garlic. Add oil. Add vinegar.

Method 1 <u>does not</u> create a food safety hazard. Method 2 <u>does create</u> a food safety hazard. In method 1, the vinegar is added to the garlic to lower the pH below 4.6 to control for *Clostridium botulinum*. In method 2, the oil is placed on the garlic first, coating the garlic and preventing the vinegar from lowering the pH.

#### Additional sources of information

US Food and Drug Administration 300 River Place, Suite 5900 Detroit, MI. 48207 (313) 393-8100 (313) 393-8137 fax US Department of Agriculture Food Safety and Inspection Service 25900 Greenfield Rd. Oak Park, MI 48237 (248) 968-0230

US Department of Agriculture Food Safety and Inspection Service 678 Front Ave. NW., Suite 400 Grand Rapids, MI 49504 (616) 458-0915

Starting a Food Business in Minnesota, <a href="http://www.mda.state.mn.us/dairyfood/startingfoodbiz.pdf">http://www.mda.state.mn.us/dairyfood/startingfoodbiz.pdf</a>
This document has general checklists, strategies and tips on starting a food business, writing a business plan, etc.

An excellent article titled "From Restaurants to Retail", April 05. http://www.restaurant.org/rusa/magArticle.cfm?ArticleID=741

HACCP plan information: <a href="http://www.nal.usda.gov/fnic/foodborne/haccp/index.shtml">http://www.nal.usda.gov/fnic/foodborne/haccp/index.shtml</a>.

Michigan Department of Agriculture

4

#### Jams, Jellies & Preserves- shelf stable

## **Applicable regulations:**

- -21 CFR 110- Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food
- -Michigan Food Law (MFL) and 1999 FDA Food Code (FC).
- -21 CFR 150- Fruit butter, jellies, preserves and related products (i.e. standard of identity)

# Establishments wishing to process jams, jellies and preserves on-site <u>must</u> complete these steps:

- 1. Have adequate space and equipment for the proposed processing operation.
- 2. Receive local health department plan approval for any construction or remodeling.
- 3. Establish standard operating procedures (SOP's) prior to beginning processing operations. Standardized procedures are essential for an establishment to comply with applicable regulations and produce a consistently safe product. Written SOP's are encouraged for all processing operations. Written SOP's are required for facilities seeking plan approval. See MDA's "Plan Submission Instructions" for SOP guidance at: <a href="http://www.mda.state.mi.us/industry/fooddata/FSSS/0411">http://www.mda.state.mi.us/industry/fooddata/FSSS/0411</a> SOP Guidance Memo.pdf
- 4. Complete any specialized training of personnel needed to conduct the proposed processing operations.
- Provide coding on containers to enable positive lot identification. Product must be marked with a visible meaningful code to enable positive lot identification and to facilitate, where necessary, the segregation of specific lots that may have become contaminated or are otherwise unfit for their intended use. Lot codes can be sell-by dates. (MFL 8109)
- 6. Properly label the product. The various laws that must be met in respect to labeling are listed in MFL 8101. A good method for a new processor to determine basic label requirements is to:
  - a. review the MDA labeling guide at: <a href="http://www.michigan.gov/mda/0,1607,7-125-1568">http://www.michigan.gov/mda/0,1607,7-125-1568</a> 2388-15868--,00.html. FDA labeling information may be viewed at: <a href="http://www.cfsan.fda.gov/label.html">http://www.cfsan.fda.gov/label.html</a>
  - b. review labels of other similar commercially packaged products. The information on the front, side and back panels would be a good indication of the information needed of the front, side and back panels of the proposed product. Remember that product ingredients must be listed in the order of major to minor ingredients, by weight.

Specific labeling requirements for jams and jellies are:

- The Statement of Identity: (the product identity) must be the common or usual name of the food, if it has one. Example: Jam, Jelly, Preserve
- Artificially flavored: When artificial flavorings are used, the product name must be accompanied by the phrase "artificially flavored" or "artificial".
   Example: "Artificial Strawberry Flavored Jam".

## Jams, Jellies & Preserves- shelf stable

- Fanciful terms: Fanciful terms are not encouraged since they are often
  confusing to the consumer. However, they may be used as a supplement to a
  proper statement of identity and are in no way false or misleading. For
  example, a label may read "Belly Bomber Strawberry Jam" (but not "Belly
  Bomber" by itself).
- **Imitation**: A food that is an imitation of another food must be labeled, in type of uniform size and prominence, with the word "imitation" immediately followed by the name of the food imitated [MCLA 289.717 (c)]. Any product that resembles and substitutes for a traditional food and contains less nutritional value than the traditional food is considered to be an imitation [21 CFR § 101.3 (e)(1)]. Example: "Imitation Strawberry Jam".
- Name and address of a responsible party: Must be declared as a unit and not separated by other label information. The address must include street address, city, state, and zip code. However, if the street address is listed in a current city or telephone directory under the responsible party name, the street address may be omitted on the label. If the responsible party is other than the manufacturer, the name must be qualified by a term describing the relationship to the product [MCLA 289.717 (e), R285.551.13, and 21 CFR § 101.5].
- **Quantity declaration**: Must be placed on the principal display panel (PDP) in the lower third of the panel. It must be printed in the required minimum type size and surrounded by sufficient clear space. Example: 12 oz.
- Ingredient list: A food product made from more than one ingredient must bear a complete list of ingredients in order of descending predominance by weight. Ingredients must be listed by their common or usual name. Spices and flavorings may be declared by the generic term "spices" or "flavorings" (artificial flavorings must be identified as artificial). Preservatives must have their function declared (for example, "preserved with for ").
- Colorings: All certified colors must be listed in the ingredient statement by their common name (e.g. FD&C Blue No. 1). Non-certified and natural colors may still be listed by the generic term "colorings."
- **Type size**: All required information must be printed in a type size of at least 1/1 6-inch in height [21 CFR § 101.2 (c)]. Other specific requirements may apply which require type size larger than 1/16 inch, and all required information must be conspicuous and easy to read.
- **Positive lot identification:** Product must be marked with a visible meaningful code to enable positive lot identification and to facilitate, where necessary, the segregation of specific lots that may have been become contaminated or are otherwise unfit for their intended use. (MFL 8109)

## Sandwiches- refrigerated

## **Applicable regulations:**

- -21 CFR 110- Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food
- -Michigan Food Law (MFL)
- -1999 FDA Food Code (FC).

# Establishments wishing to process sandwiches on-site <u>must</u> complete these steps:

- 1. Have adequate space and equipment for the proposed processing operation.
- 2. Receive local health department plan approval for any construction or remodeling.
- 3. Establish standard operating procedures (SOP's) prior to beginning processing operations. Standardized procedures are essential for an establishment to comply with applicable regulations and produce a consistently safe product. Written SOP's are encouraged for all processing operations. Written SOP's are required for facilities seeking plan approval. See MDA's "Plan Submission Instructions" for SOP guidance at: <a href="http://www.mda.state.mi.us/industry/fooddata/FSSS/0411">http://www.mda.state.mi.us/industry/fooddata/FSSS/0411</a> SOP Guidance Memo.pdf
- 4. Complete any specialized training of personnel needed to conduct the proposed processing operations.
- 5. Properly label the product. The various laws that must be met in respect to labeling are listed in MFL 8101. A good method for a new processor to determine basic label requirements is to:
  - a. review the MDA labeling guide at: <a href="http://www.michigan.gov/mda/0,1607,7-125-1568\_2388-15868--,00.html">http://www.michigan.gov/mda/0,1607,7-125-1568\_2388-15868--,00.html</a>. FDA labeling information may be viewed at: <a href="http://www.cfsan.fda.gov/label.html">http://www.cfsan.fda.gov/label.html</a>
  - b. review labels of other similar commercially packaged products. The information on the front, side and back panels would be a good indication of the information needed of the front, side and back panels of the proposed product. Remember that product ingredients must be listed in the order of major to minor ingredients, by weight.
- 6. Provide coding on containers to enable positive lot identification. Product must be marked with a visible meaningful code to enable positive lot identification and to facilitate, where necessary, the segregation of specific lots that may have become contaminated or are otherwise unfit for their intended use. Lot codes can be sell-by dates. (MFL 8109)
- 7. Obtain a variance if reduced oxygen packaging is proposed unless FC 3-502.12 is met. See FC 3-502.11-12. The person requesting the variance shall provide: A) A statement of the proposed variance of the Code requirement citing relevant Code section numbers. B) An analysis of the rationale for how the potential public health hazards and nuisances addressed by the relevant Code sections will be alternatively addressed by the proposal, and C) A HACCP plan if required. A hazard analysis control plan (HACCP) is required when 1. reduced oxygen packaging will be used and 2. **Clostridium botulinum** must be controlled for in the final packaged form of the food. (FC 3-501.12, 8-201.13 & .14)

## Sandwiches- refrigerated

- 8. Provide a last date of sale. The Michigan Food Law of 2000 (Act No. 92 of 2000, as amended) provides in Section 8107 (6) that a person who prepackages a perishable food shall do all of the following:
  - a. Establish a meaningful date that takes into consideration the food quality and characteristics of the food, its packaging, and customary conditions encountered in commercial channels.
  - b. Allow a reasonable period after the date for consumption of the food without physical spoilage.
  - c. Keep a record of the method of determination of the date.

The Act also provides in Section 8107 (8) that the date shall not be altered and that a person shall not rewrap or repackage a perishable food, in its original form and texture, with a date on the package different from the original. Finally, the Act provides in Section 8107 (9) that the date shall be calculated to allow a reasonable period for the subsequent consumption of the food but shall not allow for a period which would result in a health nuisance as described in Section 2107.

Data published by the United States Department of Agriculture demonstrates that a temperature of 41° F or below will limit the growth of the pathogen *Listeria monocytogenes* for a period up to seven days. Therefore, manufacturers of perishable sandwiches and related products intended for distribution at retail that claim a "sell-by date" longer than seven days from the date of manufacture shall provide evidence to support that claim to the Michigan Department of Agriculture.

#### Low Acid or Acidified Foods\*

Low acid: Examples are canned vegetables, antipasto (depending on recipe), canned fish, poultry, meats, some soups or other liquid food. These foods have a finished equilibrium pH of >4.6,  $A_W$  >0.85 and food is thermally processed, commercially sterile, packaged in a hermetically sealed container and is shelf stable.

Acidified: Examples are salsa, pickled eggs, pickled beets, antipasto (depending on recipe). These foods start at a pH >4.6 but with the addition of vinegar or spice solution have a finished equilibrium of pH  $\leq$ 4.6.

# Processing these types of foods can be complicated and expensive. Two methods of simplifying this experience for a food service operator are:

- Use a co-packer (hiring a custom packing company that specializes in processing and packaging foods for others). Co-packers already have training, equipment, contacts for packaging, etc. To find a co-packer, contact an association associated with the proposed product or contact the "MSU Cooperative Extension Service", (http://www.msue.msu.edu/msue/ctyentpg/ctyunits.html).
- 2. **Store**, **distribute** and **retail foods under refrigeration**. Properly label the product and provide a last date of sale. See sections 7-9 below.

#### Applicable regulations:

- -21 CFR 110- Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food
- -21 CFR 113- Thermally Processed Low-Acid Foods in Hermetically Sealed Containers
- -21 CFR 114- Acidified Foods
- -Michigan Food Law (MFL)
- -1999 FDA Food Code (FC)

# Establishments wishing to process acidified or low-acid food on-site <u>must</u> complete these steps:

- 1. Have adequate space and equipment for the proposed processing operation. Provide necessary specialized equipment, such as: retorts, pH meters, can seamers, fillers, dud detectors, etc.
- 2. Receive local health department plan approval for any construction or remodeling.
- 3. Attend "Better Processing Control School". Course list available at: http://www.fpi-food.org/courseschedule.cfm
- 4. Register and file a scheduled process with FDA. Information on this process can be found at: <a href="http://www.cfsan.fda.gov/~comm/lacf-toc.html">http://www.cfsan.fda.gov/~comm/lacf-toc.html</a>. Work in conjunction with a process specialist to develop a scheduled process (21 CFR 113.3(r) or 21 CFR 114.3(e)). Methods of locating locate a process specialist include: conducting an internet search, contact the "MSU Cooperative Extension Service".

  (<a href="http://www.msue.msu.edu/msue/ctyentpg/ctyunits.html">http://www.msue.msu.edu/msue/ctyentpg/ctyunits.html</a>) or contact a related processor's association. FDA conducts a technical edit of scheduled processes and responds in writing.
- 5. Apply for and obtain a variance from the local health department, if required. Variances are required if the proposed process includes: curing food, using additives such as vinegar for preservation or to render a food not potentially hazardous or when using reduced oxygen packaging that does not comply with 3-502.12. See FC 3-502.11 and 8-103.10-11. The person requesting the variance shall provide: A) A statement of the proposed variance of the Code requirement citing relevant Code section numbers. B) An analysis of the rationale for how the potential public health hazards and nuisances addressed by the relevant Code sections will be alternatively addressed by the proposal,

- and C) A HACCP plan if required. A hazard analysis control plan (HACCP) is required when 1. reduced oxygen packaging will be used <u>and</u> 2. *Clostridium botulinum* must be controlled for in the final packaged form of the food. (FC 3-502.12, 8-201.13 & .14)
- 6. Complete any specialized training of personnel needed to conduct the proposed processing operations.
- 7. Properly label the product. The various laws that must be met in respect to labeling are listed in MFL 8101. A good method for a new processor to determine basic label requirements is to:
  - a. review the MDA labeling guide at: <a href="http://www.michigan.gov/mda/0,1607,7-125-1568">http://www.michigan.gov/mda/0,1607,7-125-1568</a> 2388-15868--,00.html. FDA labeling information may be viewed at: <a href="http://www.cfsan.fda.gov/label.html">http://www.cfsan.fda.gov/label.html</a>
  - b. review labels of other similar commercially packaged products. The information on the front, side and back panels would be a good indication of the information needed of the front, side and back panels of the proposed product. Remember that product ingredients must be listed in the order of major to minor ingredients, by weight.
- Provide coding on containers to enable positive lot identification. Product must be marked with a visible meaningful code to enable positive lot identification and to facilitate, where necessary, the segregation of specific lots that may have become contaminated or are otherwise unfit for their intended use. Lot codes can be sell-by dates. (MFL 8109)
- 9. Provide a last date of sale, if the shelf life of the product is less than 90 days. The Michigan Food Law of 2000 (Act No. 92 of 2000, as amended) provides in Section 8107 (6) that a person who prepackages a perishable food shall do all of the following:
  - Establish a meaningful date that takes into consideration the food quality and characteristics of the food, its packaging, and customary conditions encountered in commercial channels.
  - b. Allow a reasonable period after the date for consumption of the food without physical spoilage.
  - c. Keep a record of the method of determination of the date.

The Act also provides in Section 8107 (8) that the date shall not be altered and that a person shall not rewrap or repackage a perishable food, in its original form and texture, with a date on the package different from the original. Finally, the Act provides in Section 8107 (9) that the date shall be calculated to allow a reasonable period for the subsequent consumption of the food but shall not allow for a period which would result in a health nuisance as described in Section 2107.

Data published by the United States Department of Agriculture demonstrates that a temperature of 41° F or below will limit the growth of the pathogen *Listeria monocytogenes* for a period up to seven days. Therefore, manufacturers of perishable products intended for distribution at retail that claim a "sell-by date" longer than seven days from the date of manufacture shall provide evidence to support that claim to the Michigan Department of Agriculture.

#### \*USDA

Contact USDA for approvals if the product will include at least 2% cooked or 3% raw meat or poultry, by weight. USDA will oversee the approvals for the product and establishment. An onsite USDA inspector is required for these products (9 CFR 318). When USDA handles oversight of these products, then MDA is only involved in regulating retail sale, storage and display. USDA may grant an exemption from their regulations for a food service establishment that processes food. USDA, Food Safety and Inspection Service (FSIS) may be contacted at Oak Park, MI. (248) 968-0230.

# Soups- refrigerated or frozen\* Pizza- refrigerated or frozen\*

# **Applicable regulations:**

- -21 CFR 110- Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food
- -Michigan Food Law (MFL)
- -1999 FDA Food Code (FC).

# Establishments wishing to process pizza / soups on-site <u>must</u> complete these steps:

- 1. Have adequate space and equipment for the proposed processing operation. Provide necessary specialized equipment.
- 2. Receive local health department plan approval for any construction or remodeling.
- 3. Establish standard operating procedures (SOP's) prior to beginning processing operations. Standardized procedures are essential for an establishment to comply with applicable regulations and produce a consistently safe product. Written SOP's are encouraged for all processing operations. Written SOP's are required for facilities seeking plan approval. See MDA's "Plan Submission Instructions" for SOP guidance at: <a href="http://www.mda.state.mi.us/industry/fooddata/FSSS/0411">http://www.mda.state.mi.us/industry/fooddata/FSSS/0411</a> SOP Guidance Memo.pdf
- 4. Complete any specialized training of personnel needed to conduct the proposed processing operations.
- 5. Properly label the product. The various laws that must be met in respect to labeling are listed in MFL 8101. A good method for a new processor to determine basic label requirements is to:
  - d. review the MDA labeling guide at: <a href="http://www.michigan.gov/mda/0,1607,7-125-1568">http://www.michigan.gov/mda/0,1607,7-125-1568</a> 2388-15868--,00.html. FDA labeling information may be viewed at: <a href="http://www.cfsan.fda.gov/label.html">http://www.cfsan.fda.gov/label.html</a>
  - e. review labels of other similar commercially packaged products. The information on the front, side and back panels would be a good indication of the information needed of the front, side and back panels of the proposed product. Remember that product ingredients must be listed in the order of major to minor ingredients, by weight.
- 6. Provide coding on containers to enable positive lot identification. Product must be marked with a visible meaningful code to enable positive lot identification and to facilitate, where necessary, the segregation of specific lots that may have become contaminated or are otherwise unfit for their intended use. Lot codes can be sell-by dates. (MFL 8109)

# Soups- refrigerated or frozen\* Pizza- refrigerated or frozen\*

- 7. Provide a last date of sale, if the shelf life of the product is less than 90 days. The Michigan Food Law of 2000 (Act No. 92 of 2000, as amended) provides in Section 8107 (6) that a person who prepackages a perishable food shall do all of the following:
  - Establish a meaningful date that takes into consideration the food quality and characteristics of the food, its packaging, and customary conditions encountered in commercial channels.
  - b. Allow a reasonable period after the date for consumption of the food without physical spoilage.
  - c. Keep a record of the method of determination of the date.

The Act also provides in Section 8107 (8) that the date shall not be altered and that a person shall not rewrap or repackage a perishable food, in its original form and texture, with a date on the package different from the original. Finally, the Act provides in Section 8107 (9) that the date shall be calculated to allow a reasonable period for the subsequent consumption of the food but shall not allow for a period which would result in a health nuisance as described in Section 2107.

Data published by the United States Department of Agriculture demonstrates that a temperature of 41° F or below will limit the growth of the pathogen *Listeria monocytogenes* for a period up to seven days. Therefore, manufacturers of perishable refrigerated soups intended for distribution at retail that claim a "sell-by date" longer than seven days from the date of manufacture shall provide evidence to support that claim to the Michigan Department of Agriculture.

#### \*USDA

Contact USDA for approvals if the product will include at least 2% cooked or 3% raw meat or poultry, by weight. USDA will oversee the approvals for the product and establishment. An on-site USDA inspector is required for these products (9 CFR 318). When USDA handles oversight of these products, then MDA is only involved in regulating retail sale, storage and display. USDA may grant an exemption from their regulations for a food service establishment that processes food. USDA, Food Safety and Inspection Service (FSIS) may be contacted at Oak Park, MI. (248) 968-0230.

# Dry Shelf Stable Foods, such as: Baked Goods- refrigerated, frozen or shelf stable Dry Snack Foods- refrigerated or shelf stable Candy

# **Applicable regulations:**

- -21 CFR 110- Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food
- -Michigan Food Law (MFL)
- -1999 FDA Food Code (FC).

# Establishments wishing to process these foods on-site <u>must</u> complete these steps:

- 1. Have adequate space and equipment for the proposed processing operation. Provide necessary specialized equipment.
- 2. Receive local health department plan approval for any construction or remodeling.
- 3. Establish standard operating procedures (SOP's) prior to beginning processing operations. Standardized procedures are essential for an establishment to comply with applicable regulations and produce a consistently safe product. Written SOP's are encouraged for all processing operations. Written SOP's are required for facilities seeking plan approval. See MDA's "Plan Submission Instructions" for SOP guidance at: <a href="http://www.mda.state.mi.us/industry/fooddata/FSSS/0411">http://www.mda.state.mi.us/industry/fooddata/FSSS/0411</a> SOP Guidance Memo.pdf
  - Complete any appointing of personnel peeded to conduct the proposed
- 4. Complete any specialized training of personnel needed to conduct the proposed processing operations.
- 5. Properly label the product. The various laws that must be met in respect to labeling are listed in MFL 8101. A good method for a new processor to determine basic label requirements is to:
  - a. review the MDA labeling guide at: <a href="http://www.michigan.gov/mda/0,1607,7-125-1568">http://www.michigan.gov/mda/0,1607,7-125-1568</a> 2388-15868--,00.html. FDA labeling information may be viewed at: <a href="http://www.cfsan.fda.gov/label.html">http://www.cfsan.fda.gov/label.html</a>
  - b. review labels of other similar commercially packaged products. The information on the front, side and back panels would be a good indication of the information needed of the front, side and back panels of the proposed product. Remember that product ingredients must be listed in the order of major to minor ingredients, by weight.
- 6. Provide coding on containers to enable positive lot identification. Product must be marked with a visible meaningful code to enable positive lot identification and to facilitate, where necessary, the segregation of specific lots that may have become contaminated or are otherwise unfit for their intended use. Lot codes can be sell-by dates. (MFL 8109)

# Dry Shelf Stable Foods, such as: Baked Goods- refrigerated, frozen or shelf stable Dry Snack Foods- refrigerated or shelf stable Candy

- 7. Provide a last date of sale, if the shelf life of the product is less than 90 days. The Michigan Food Law of 2000 (Act No. 92 of 2000, as amended) provides in Section 8107 (6) that a person who prepackages a perishable food shall do all of the following:
  - a. Establish a meaningful date that takes into consideration the food quality and characteristics of the food, its packaging, and customary conditions encountered in commercial channels.
  - b. Allow a reasonable period after the date for consumption of the food without physical spoilage.
  - c. Keep a record of the method of determination of the date.

The Act also provides in Section 8107 (8) that the date shall not be altered and that a person shall not rewrap or repackage a perishable food, in its original form and texture, with a date on the package different from the original. Finally, the Act provides in Section 8107 (9) that the date shall be calculated to allow a reasonable period for the subsequent consumption of the food but shall not allow for a period which would result in a health nuisance as described in Section 2107.

Note: Alcohol-filled confections not allowed (MFL 1105(xii)).

# **Processing Information Sheet**

Food service establishment proposing processing	ng		
Contact person	Phone	Date	
Product Identity (describe product in detail)			
On site process category			
On-site process category			
<ul><li>Not heat treated (shelf stable) (CFR 110)</li><li>Heat treated, but not fully cooked, not shelf</li></ul>	stable		
( refrigerated, frozen) (CFR 110) Fully cooked, shelf stable (CFR 110 and 11			
Fully cooked, not shelf stable ( refrigera	ited, froze		
Other			
Intended Use			
Ready-to-eat			
<ul><li>Further preparation required before consun</li><li>Raw</li></ul>	nption		
Packaging			
Vacuum packaging			
Other			
Type of container and lid			
Intended Storage / Shelf Life			
Refrigerated			
Frozen Shelf stable			
Shelf life			
Method of sale:			
Labeling Instructions:			
Special distribution control needed:			
Other food operations or non-food operation	ns conducted:		

## Specialized Processing Methods, Variance Requirement – 3-502.11 See variance documentation requirements in 8-103.10 & 11

Specialized processing	Food Code sections that may be	Documents to review
methods requiring a variance	requested for a variance	
-Smoking food for preservation -Curing food -Using food additives for preservation or render food non- potentially hazardous	FC 3-501.17 & 18, Date Marking FC 3-401.11, Cooking FC 3-501.16(b), Cold Holding FC 3-501.16(a), Hot Holding	Necessary variance request documentation may vary with the specific processing proposal.  Documents may include:  variance request form.
Reduced oxygen packaging (ROP)	FC 3-501.17 & 18, Date Marking FC 3-502.12, Reduced Oxygen Packaging Criteria, when a ROP method is used where only one barrier is in place to control the growth and toxin formation of <i>Clostridium botulinum</i>	<ul> <li>detailed materials from the applicant that describes the process, packaging, associated food safety hazards and proposed controls.</li> <li>Standard operating procedures and quality control plans.</li> <li>a HACCP plan if required.</li> <li>peer reviewed scientific research (i.e. articles from food safety journals).</li> <li>scheduled process materials that would be filed with FDA for low-acid and acidified products (see the sheet labeled "low acid or acidified foods" for more information on scheduled processes).</li> <li>written FDA response to scheduled process filings.</li> <li>Local health department staff should consult with their MDA</li> </ul>
Custom processing of animals for personal use.	FC 3-201.11(A), Approved Source	
		<ul><li>on scheduled p</li><li>written FDA res</li><li>scheduled proc</li><li>Local health depart</li></ul>

Variance requests and necessary documentation will vary with the specific processing method or combination of methods being proposed.

The person requesting the variance shall provide: A) A statement of the proposed variance of the Code requirement citing relevant Code section numbers. B) An analysis of the rationale for how the potential public health hazards and nuisances addressed by the relevant Code sections will be alternatively addressed by the proposal, and C) A HACCP plan if required. A hazard analysis control plan (HACCP) is required when 1. reduced oxygen packaging will be used and 2. *Clostridium botulinum* must be controlled for in the final packaged form of the food. (FC 3-502.12, 8-201.13 & .14)